



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/740,209

12/18/2000

Jaan Noolandi

A0489-US-NP

4337

81941

7590

10/05/2009

PARC-XEROX/BSTZ

BLAKELY SOKOLOFF TAYLOR & ZAFMAN LLP

1279 Oakmead Parkway

Sunnyvale, CA 94085-4040

EXAMINER

BLIZZARD, CHRISTOPHER JAMES

ART UNIT

PAPER NUMBER

3771

MAIL DATE

DELIVERY MODE

10/05/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

1. This office action is in response to amendment filed 6/18/09. As directed claims 1-7, 9, 11, 13, 14, 24-26 were amended, claims 8, 18 and 20 were cancelled, and no claims were added. Therefore this application currently has claims 1-7, 9-17, 19, 21-26 pending.

Drawings

2. The amendment to figure 4 filed on 6/18/09 is acknowledge. However, the addition of the UV source (430) does not show the structural relationship with the device, and thus renders the drawings not acceptable.

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “Fresnel lens”, “multiplexing circuit” and “sterilization mechanism” as cited in the claims must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

Art Unit: 3771

of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 2, 9, 19, 23 and 26 are rejected under 35 U.S.C. 102(a/e) as being anticipated by Babev (6,601,581).

6. Regarding claims 1, 9 and 26, Babev discloses an apparatus for delivering a pharmaceutical product (18) comprising; a first driver element (15) to generate acoustic energy in pulses (column 4, line 25) that are of a short duration and a low frequency, in a range of 18 kHz to 10,000 MHz (column 4, lines 19, 24), such that droplets (10) of pharmaceutical product is output from a capillary wave (column 1, lines 22-27); a first acoustic lens (13) to focus the acoustic energy generated by the driver (column 4, lines

55-56); and a delivery system (17) to maintain the pharmaceutical product in a position to receive the acoustic energy from the acoustic lens (fig. 2).

7. Regarding claim 2, Babev discloses a portable source (22) of electrical power coupled to the first driver element (15) (fig. 2) (column 4, lines 62-66).

8. Regarding claim 19, Babev discloses a section (25) for insertion into a human orifice to increase amount of pharmaceutical product delivered to a patient (column 5, lines 3-5).

9. Regarding claim 23, Babev discloses the claimed method in claim 19.

10. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Humberstone (5,823,428).

11. Regarding claim 11, Humberstone discloses an apparatus for delivering a pharmaceutical product (91) (column 2, lines 51-53) comprising a driver element (72) to generate acoustic energy below 15 MHz (column 6, lines 9-11) and thereby generate a capillary wave (column 7, lines 18-20); and acoustic lens (53) to focus the acoustic energy generated by the driver (fig. 6e), a delivery system to maintain the pharmaceutical production in a position to receive the acoustic energy from the acoustic lens and cause ejection of a droplet of pharmaceutical production, the delivery system including a pressurization system that control the pressure of the pharmaceutical product (column 6, lines 29-32).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3771

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Babev (6,601,581)

15. Regarding claim 10, Babev discloses a range of droplet diameters to be .1 micron to several millimeters (column 1, lines 57-60). Thus, Babev has the claimed diameter.

16. Claim 3-6, 14-16 and are rejected under 35 U.S.C. 103(a) as being unpatentable over Babev (6,601,581) in view of Rawson (5,339,101).

17. Regarding claims 5, 6, and 14, Babev discloses an apparatus to output a pharmaceutical product (18) comprising; a portable energy supply (22), a transducer (15) coupled to the power supply (fig. 2) (column 4, lines 62-66) that output acoustic energy in a range of 18 kHz to 10,000 MHz (column 4, lines 19, 24), such that droplets (10) of pharmaceutical product are output from a capillary wave (column 1, lines 22-

Art Unit: 3771

27); an acoustic lens (13) to focus the acoustic energy generated by the transducer (column 4, lines 55-56); and a delivery system (17) to maintain the reservoir (18,19) of pharmaceutical product, a distance from a top surface of a lens (13) and a surface of the reservoir is 50 microns (column 4, lines 45-47), the reservoir of pharmaceutical production to receive energy from the lens to cause ejection of a plurality of droplets a distance from the top surface of the lens (column 4, lines 51-56).

Babev does not disclose a plurality of lenses or a secondary driver element. Rawson et al. discloses a plurality of lenses (15) each attached to a driver unit (12) (fig. 2). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the apparatus of Babev with a plurality of lenses each attached to a driver element as taught by Rawson in order to provide the advantage of delivering more pharmaceutical at once.

18. Regarding claims 3, 4, 15, and 16, the modification of Babev by Rawson contains plastic Fresnel lens, taught by Rawson (column 2, line 1)

19. Regarding claim 22, the modification of Babev by Rawson above discloses the claimed limitations, wherein Babev discloses the ejected droplets having a diameter less than 5 micrometers.

20. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Babev (6,601,581) in view of Sweet (5,832,428).

21. Regarding claims 6 and 7, Babev does not disclose a second driver element, a second acoustic lens or a multiplexing circuit. Sweet discloses a second driver element (15) (fig. 3), a second lens (19) (fig. 3) wherein a multiplexing circuit (41) can direct RF

Art Unit: 3771

energy from an energy source to any combination of driver elements, and thus will alternately switch group of ejectors on and off (column 3, lines 47-49). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the apparatus of Babev with a second lens and driver element attached to a multiplexing circuit as taught by Sweet in order to provide the advantage of delivering a more specific amount of pharmaceutical during any span of time.

22. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Babev (6,601,581) in view of Hodson (6,012,454).

23. Regarding claim 13, Babev does not disclose a MEMS cover that protects the driver element from contamination when the drive is not outputting acoustic energy. Hodson et al. discloses an inhaler with a cover (47) that prevents contamination when not in use (column 15, lines 44-50). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the apparatus of Babev with a cover as taught by Hodson in order to provide the advantage of protecting the inner components from contamination.

24. Claims 21, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Babev (6,601,581) in view of Elrod ("Nozzless droplet...").

25. Regarding claims 21, 24 and 25, Babev does not disclose the formation of capillary waves by relaxation of a principle mound. Elrod et al. teaches the formation of capillary waves from a principal mound (p. 3441, introduction, toward end of second paragraph) and the aerosol formed by the resulting capillary waves (p. 3444, Pulse Width: Ejection Stability and Droplet Diameter, first paragraph). Therefore it would have

Art Unit: 3771

been obvious to one of ordinary skill at the time the invention was made to provide Babev's invention with the description of the formation of capillary waves as taught by Elrod et al. in order to provide the advantage of optimizing pharmaceutical output.

26. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Babev (6,601,581) in view of Rawson (5,339,101) as applied to claim 14 above, and further in view of Ivri (6,205,999).

27. Regarding claim 17, the modification of Babev by Rawson does not disclose a circuit that detects air flow into a patient's lungs. Ivri teaches a flow sensor (24) (fig. 2) for detecting flow into a patient (column 7, lines 51-53) that couples to a transducer (26) to a circuit (column 7, lines 53-56). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the apparatus of Babev with a sensor as taught by Ivri in order to provide the advantage of preventing accidental dosing of pharmaceutical product.

28. Claims 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Humberstone (5,823,428) in view of Blau (5372126)

29. Regarding claim 12, Humberstone does not disclose a sterilization mechanism. Blau discloses a sterilization mechanism that outputs ultraviolet energy for sterilization purposes (column 1, lines 48-50). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the apparatus of Humberstone with a sterilization mechanism as taught by Blau in order to provide the advantage of providing a safer means for providing pharmaceutical to a patient.

Response to Arguments

Art Unit: 3771

30. Applicant's arguments filed 6/18/09 have been fully considered but they are not persuasive. Applicant's arguments concerning objections to drawings are not persuasive because, amended fig. 4 does not properly show UV source (430) which is claimed to be a "sterilization mechanism", the claimed Fresnel lens shown as element (140) in figure 1 alone or in combination with the specification does not adequately represent a Fresnel lens, and the claimed multiplexing circuit shown as element (536) in figure 5 is stated in the specification to represent a "drive circuit" and not a multiplexing circuit. Applicant's arguments concerning the device of Babev are not persuasive because; the dispenser tube (12) does act as a delivery system of the droplet so that the droplet is positioned to receive the acoustic energy of the acoustic lens so that the droplet can be ejected from the acoustic lens, and the radiation surface (13) does act as an acoustic lens in that it focuses acoustic energy from the driver to output the liquid drop by means of a capillary wave. Further, Babev does teach that droplet diameters for 0.1 μ m to several millimeters as capable of being made using capillary waves. Applicant's arguments concerning the device of Humberstone are not persuasive because, the membrane of Humberstone is vibrated by a transducer to form capillary waves and each opening on the membrane acts as one of a plurality of lens. Applicant's arguments concerning the combination of Babev and Rawson is not persuasive because of the reasons discussed above and that Rawson discloses Fresnel lens made of polyimide (column 2, line 1), which is a plastic. Applicant's arguments concerning the combination of Babev and Sweet are not persuasive because the multiplexing circuit of Sweet inherently alternately switches group of

Art Unit: 3771

ejectors on and off in the process of exciting any sequence of transducers. Applicant's arguments concerning the combination of Babev and Hodson are not persuasive because the cover of Hodson performs all functions of the claimed MEMS cover, further the MEMS cover (416) in the specification and figure 4 appears to be of comparable size to that of Hodson. Applicant's arguments concerning the combination of Babev, Rawson and Ivri are not persuasive because the inhalation flow sensor (24) of Ivri is a circuit that detects a flow of air and would have a critical air speed when it begins to register air flow. Applicant's arguments concerning the combination of Humberstone and Blau are not persuasive because Blau teaches that Ultraviolet light has sterilization properties and does not teach away from sterilizing substances other than air.

Conclusion

31. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 3771

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BLIZZARD whose telephone number is (571)270-7138. The examiner can normally be reached on Monday thru Friday, 9:00AM -5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)2724835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER BLIZZARD/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771